REMARKS

Claims 1-5, 7-31 and 33-74 are pending. Claims 50-74 have been newly added, and claims 1, 4, 5, 7, 8, 10-15, 18-25, 27, 33-36, 38, 40-42, 44-47 and 49 have been amended for clarity only. Reconsideration and allowance of the present application based on the following remarks are respectfully requested.

In the Specification

. The disclosure is objected to because of informalities relating to the Abstract of the Disclosure. Applicants have submitted a new Abstract of the Disclosure to correct the Abstract in accordance with the suggestions of the Office Action. Accordingly, Applicants respectfully request withdrawal of the objection.

Claim Rejections Under 35 U.S.C. § 112

Claims 1, 6-11, 14, 27 and 44 were rejected under 35 U.S.C. § 112, second paragraph. This rejection is moot with respect to claim 6 because claim 6 was cancelled in the Preliminary Amendment filed June 13, 2000. With respect to claims 1 and 7-11, the Office Action indicated that it is allegedly unclear whether Applicants are claiming the combination of a substance delivery apparatus and a system for supplying a breathable gas or the subcombination of a substance delivery apparatus. The Office Action (correctly) indicates that there is a clear indication in the preamble that the Applicants intend to claim the subcombination. The Office Action alleges that Applicants go on to positively recite the combination. The claims have been amended and/or checked to ensure that elements of the subcombination are not positively recited. Thus, Applicants submit that claims 1 and 7-11 clearly recite the subcombination of a substance delivery apparatus. Further, Applicants have added new claim 74 directed to the combination of a system and substance delivery apparatus, which clearly shows that claim 1 is drawn to the subcombination. With respect to claims 1, 14, 27 and 44, Applicants have amended these claims for clarity to better comply with 35 U.S.C. § 112. Accordingly, the rejection with respect to claims 1, 7-11 (by virtue of their dependence from claim 1), 14, 27 and 44 is overcome, and claims 1, 7-11, 14, 27 and 44 are allowable.

Claim Rejections Under 35 U.S.C. § 102

Claims 1-4 and 27-30 were rejected under 35 U.S.C. § 102(e) over Briend et al. (U.S. Patent No. 5,651,358). Applicants respectfully traverse this rejection because Briend et al. fails to disclose every feature recited in the claims.

Independent claim 1 recites, in part, a substance delivery apparatus including means for delivering a substance during inhalation at a pressure that exceeds the measured pressure of a supplied pressure of the breathable gas by a predetermined pressure difference. Independent claim 27 recites, in part, a method of delivering a substance including delivering a substance during inhalation at a pressure that exceeds the pressure of a supplied pressure of the breathable gas by a predetermined pressure difference. The Office Action alleges that Briend et al. discloses an apparatus/method including means to deliver a substance to the user at a pressure that exceeds the measured pressure of the supplied air's pressure by a predetermined amount. However, Applicants respectfully submit that Briend et al. fails to disclose this feature.

Briend et al. is directed at a system/method of supplying gases to a patient and adding a controlled quantity of nitric oxide to the flow of respiratory mixture supplied by a respirator. With respect to the pressure of the nitric oxide added to the flow of respiratory mixture supplied by the respirator, Briend et al. disclose that "the duration of opening and the pressure, fixed by the expander 9, being determined so as to obtain the desired concentration of nitric oxide as a function of the current inhalation volume of the user, typically between 10 and 40 ppm." (column 2, lines 46-50). In other words, Briend et al. merely discloses that a combination of the opening duration and the pressure of the added nitric oxide is determined to obtain a desired concentration of nitric oxide as a function of the user inhalation volume. Briend et al. is silent as to any relationship between the pressure of the added nitric oxide and the pressure of the flow of respiratory mixture supplied by the respirator. Applicants submit that the desired concentration of nitric oxide in Briend et al. can be obtained merely by varying the opening duration without supplying the nitric oxide at a pressure exceeding that of the supplied respiratory mixture. Accordingly, Briend et al. fails to disclose the claimed substance delivery apparatus including means for delivering a substance at a pressure that exceeds the measured pressure of a supplied pressure of the breathable gas by a predetermined pressure difference, as recited in claim 1. Similarly, Briend et al. fails to disclose the claimed method of delivering a substance including delivering a substance at a

pressure that exceeds the pressure of a supplied pressure of the breathable gas by a predetermined pressure difference, as recited in claim 27.

Furthermore, Briend et al. discloses that "in the presence of oxygen, nitric oxide oxidizes rapidly to form nitrogen dioxide, which can lead to the formation of toxic metabolites," (column 1, lines 30-32). Accordingly, the object of the invention disclosed by Briend et al. is to supply controlled quantities of nitric oxide with total safety, without preliminary and significant premixing with the oxygen of the usual respiratory mixture (see, for example, Briend et al., column 1, lines 35-42). Applicants respectfully submit that supplying nitric oxide at a pressure that exceeds the measured pressure of the supplied pressure of the breathable gas in Briend et al. could increase the premixing of the oxygen in the respiratory mixture with the nitric oxide supplied to the respitory mixture. Accordingly, it would not be obvious to one of ordinary skill in the art to modify the teachings of Briend et al. to deliver a substance at a pressure that exceeds the pressure of a supplied pressure of the breathable gas by a predetermined pressure difference, as recited in claims 1 and 27, because it could increase oxygen/nitric oxide premixing and reduce safety.

Accordingly, Applicants submit that claims 1 and 27 are allowable, and that claims 2-4 and 28-30 are allowable at least by virtue of their dependence from claims 1 and 27, respectively.

Claim Rejections Under 35 U.S.C. § 103

Claims 5, 13, 14, 31, 37 and 38 were rejected under 35 U.S.C. § 103(a) over Briend et al. Claims 5, 13 and 14 depend directly or indirectly from independent claim 1. Claims 31, 37 and 38 depend indirectly from independent claim 27. Accordingly, Applicants submit that claims 5, 13, 14, 31, 37 and 38 are allowable over Briend et al. for at least the same reasons set forth above with respect to independent claims 1 and 27. In particular, Briend et al. fails to disclose or suggest delivering a substance at a pressure that exceeds the pressure of a supplied pressure of the breathable gas by a predetermined pressure difference as recited in claims 1 and 27, which Applicants submit would not be obvious to one skilled in the art due to the potential premixing hazard of the nitric oxide in Briend et al.

Claims 15-22 and 39-49 were rejected under 35 U.S.C. § 103(a) over Briend et al. in view of Bolt et al. (DE 19525557 A1). Applicants submit that Briend et al. fails to disclose or suggest delivering a substance at a pressure that exceeds the pressure of a supplied pressure

of the breathable gas by a predetermined pressure difference, as recited in claims 1 and 27. Bolt et al. is merely directed at a diaphragm dosing pump. Accordingly, Bolt et al. fails to remedy the deficiencies in Briend et al. Claims 15-22 depend directly or indirectly from independent claim 1. Claims 39-49 depend directly or indirectly from independent claim 27. With respect to claim 47, Applicants submit that the cited prior art references fail to disclose or suggest the claim specified feature of an "input signal indicative of the pressure difference by which the pressure of the delivered substance should exceed the pressure sof the supplied breathable gas," as recited in claim 47. Accordingly, Applicants respectfully submit that claims 15-22 and 39-49 are allowable at least by virtue of their dependence from independent claims 1 and 27, respectively, for at least the same reasons as set forth above with respect to independent claims 1 and 27.

Claims 7-12 and 33-36 were rejected under 35 U.S.C. § 103(a) over Briend et al. in view of Eichler (U.S. Patent No. 4,588,710) and Snook et al. (U.S. Patent No. 4,938,212). Applicants submit that Briend et al. fails to disclose or suggest delivering a substance at a pressure that exceeds the pressure of a supplied pressure of the breathable gas by a predetermined pressure difference, as recited in claims 1 and 27. Eichler is merely directed at testing the airways of a patient by administering aerosols during patient inhalation with an atomizer. The atomizer administers aerosols using compressed air only to supply the necessary energy to deliver the aerosols. Snook et al. is merely directed at a supplemental oxygen apparatus which yields savings in oxygen by giving a physiological equivalent of a prescribed continuous stream of oxygen. Therefore, Eichler and Snook et al. individually or in combination fail to remedy the deficiencies in Briend et al. because they fail to disclose or suggest delivering a substance at a pressure that exceeds the pressure of a supplied pressure of the breathable gas by a predetermined pressure difference, as recited in claim 1 and 27. Claims 7-12 and 33-36 depend directly or indirectly from independent claims 1 and 27, respectively. Accordingly, Applicants respectfully submit that claims 7-12 and 33-36 are allowable for at least the same reasons as set forth above with respect to independent claims 1 and 27.

Claim Rejections Under Double-Patenting

Claims 1-5, 7-31 and 33-49[1] were rejected under the judicially created Doctrine of Obviousness-Type Double Patenting over claims 1-23 of U.S. Patent No. 6,029,660 in view of Briend et al. The Office Action indicates that Briend et al. discloses means to deliver a substance to the user during inhalation at a pressure that exceeds the measured pressure of the supplied air's pressure by a predetermined amount. However, as set forth above with respect to independent claims 1 and 27, Applicants respectfully submit that Briend et al. fails to disclose or suggest delivering a substance at a pressure that exceeds the pressure of a supplied pressure of the breathable gas by a predetermined pressure difference, as recited in claim 1 and 27. In particular, Briend et al. discloses that the duration of opening and the pressure of a controlled quantity of nitric oxide is fixed by an expander 9 and determined to obtain a desired concentration as a function of the current inhalation volume of the user. Briend et al. fails to disclose that the pressure exceeds the pressure of the supplied air's pressure by a predetermined amount, as alleged in the Office Action. Furthermore, Briend et al. teaches that the risk of introducing nitric oxide into respiratory gas circuits and preliminary premixing with oxygen should be avoided (see column 2, lines 55-62). Accordingly, there would be no suggestion or motivation for one skilled in the art to introduce nitric oxide at a pressure that exceeds the measured pressure of the supplied air's pressure because it could potentially lead to increased oxidation of nitric oxide to form nitrogen dioxide, which can lead to the formation of toxic metabolites which would harm the patient. With respect to claims 23 and 47, Applicants submit that the cited prior art references fail to disclose or suggest the claim specified feature of an "input signal indicative of the pressure difference by which the pressure of the delivered substance should exceed the pressure sof the supplied breathable gas," as recited in claims 23 and 47. Accordingly, it would not have been obvious to combine the cited prior art references to obtain the instant application's claimed invention.

Newly Added Claims

Similar to claims 1 and 27, newly added claims 50-74 recite, *inter alia*, a positive displacement pump adapted to deliver a substance to the human or animal "during an inhalation at a pressure that exceeds the measured pressure of a supplied pressure of the

[1] Applicants have received a duplicate page 12 containing items 19 and 20 substantially equivalent to items 19 and 20 on the original page 12, the difference being the range of claims rejected. Because item 19 on the

breathable gas by a predetermined pressure difference." Accordingly, Applicants respectfully submit that claims 50-74 are allowable over the prior art of record for at least the same reasons set forth above with respect to claims 1 and 27.

CONCLUSION

In view of the foregoing, all the claims are now believed to be in form for allowance, and such action is hereby solicited. If any point remains in issue which the Examiner feels may be best resolved through a personal or telephone interview, please contact the undersigned at the telephone number listed below.

Attached is a marked-up version of the changes made to the specification and claims by the current amendment. The attached Appendix is captioned **"Version with markings to show changes made"**.

All objections and rejections having been addressed, it is respectfully submitted that the present application is in a condition for allowance and a Notice to that effect is earnestly solicited.

Respectfully submitted,

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Enclosure: Appendix

duplicate page 12 includes a rejection with a range including claims 6 and 32 which were previously cancelled, Applicants will disregard the second duplicate page 12 as a typographical error.

APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 1, 4, 5, 7, 8, 10-15, 18-25, 27, 33-36, 38, 40-42, 44-47 and 49 are amended as follows:

1. (Twice Amended) A substance delivery apparatus for use with a system for supplying breathable gas pressurized above atmospheric pressure to a human or animal, the apparatus including:

means [to] for continuously [measure] measuring the pressure of [the] a supplied breathable gas;

means [to detect] for detecting inhalation by the human or animal; and

means [to deliver the] for delivering a substance to the human or animal during [the] an inhalation at a pressure that exceeds the measured pressure of [the] a supplied pressure of the breathable gas by a predetermined [amount] pressure difference.

4. (Amended) An apparatus as claimed in claim 1, wherein the means for delivering the substance is [delivered] adapted to deliver the substance to the respiratory system of the human or animal.

5. (Amended) An apparatus as claimed in claim 4, wherein the means for delivering the substance is [delivered] adapted to deliver the substance to the nasal airways of the human or animal.

7. (Amended) An apparatus as claimed in claim 1, wherein the [system for supplying breathable gas includes a pressurized gas flow generator in fluid communication with a mask worn by the human or animal via a flexible conduit, and the inhalation detection] means for detecting inhalation includes an airflow sensor adapted to measure [the] a volumetric flow rate of the breathable gas passing through [the] a flexible conduit in fluid communication with a pressurized gas flow generator and a mask adapted to be worn by the human or animal and being adapted to generate a first input signal indicative of the breathable gas flow rate.

8. (Amended) An apparatus as claimed in claim 7, further including [a first] an amplifier to amplify the first input signal into a second input signal also indicative of the breathable gas flow rate.

10. (Amended) An apparatus as claimed in claim 7, wherein [the mask includes a gas washout vent to atmosphere and] the airflow sensor is adapted to be disposed downstream of [the] a gas washout vent to atmosphere of the mask such that inhalation can be detected by sensing a reversal of the direction of the breathable gas flow through the vent.

11. (Amended) An apparatus as claimed in claim 10, wherein the airflow sensor is adapted to detect inhalation [is detected] by sensing an interruption of the breathable gas flow through the vent.

12. (Amended) An apparatus as claimed in claim 1, further including means [to measure] for measuring the volume of the substance to be delivered to the human or animal.

13. (Amended) An apparatus as claimed in claim 1, wherein the [pressure measuring] means for continuously measuring the pressure is a pressure transducer adapted to be connected to [the] a conduit in fluid communication with a pressurized gas flow generator and a mask adapted to be worn by the human or animal, said transducer being adapted to generate a fourth input signal indicative of the pressure of the breathable gas in the conduit.

14. (Amended) An apparatus as claimed in claim 13, including [a second] an amplifier to amplify the fourth input signal into a fifth input signal also indicative of the breathable gas pressure.

15. (Amended) An apparatus as claimed in claim 1, wherein the [substance delivery] means for delivering a substance is a positive displacement pump.

18. (Amended) An apparatus as claimed in claim 16, wherein the diaphragm pump is adapted to be in fluid communication with the gas supply conduit via a one-way valve adapted to allow the substance to only pass from the diaphragm pump to the conduit.

19. (Amended) An apparatus as claimed in claim 16, wherein the diaphragm pump is displaced by a linear drive [means].

20. (Amended) An apparatus as claimed in claim 19, wherein the linear drive [means] is an electromagnet.

21. (Amended) An apparatus as claimed in claim 16, wherein the diaphragm of the diaphragm pump is displaced by a rotary to linear converter driven by a rotary drive [means].

22. (Amended) An apparatus as claimed in claim 21, wherein the rotary drive [means] is one of an electric DC motor, an electric AC motor, a stepper motor [or] and a brushless motor.

23. (Amended) An apparatus as claimed in claim 19, further including a first control system having input means [adapted to allow] for allowing the input of a predetermined sixth input signal indicative of the volume of the substance to be delivered and a predetermined seventh input signal indicative of the [amount] pressure difference by which the pressure of the delivered substance should exceed the pressure of the supplied breathable gas, said first control system being adapted to receive the second, third, fifth, sixth and seventh input signals and calculate and generate a first output signal indicative of the amount of displacement of the linear drive or the rotary drive [means] and a second output signal indicative of the direction of the displacement required to produce a negative or positive pumping pressure.

24. (Amended) An apparatus as claimed in claim 23, wherein a negative pumping pressure draws the substance from the substance reservoir into the pump and a positive pumping pressure expels the substance from the pump to [the] a flexible conduit and

so to a mask in fluid communication with the conduit and adapted to be worn by the human or animal.

25. (Amended) An apparatus as claimed in claim 24, wherein the first and second output signals are sent to a second control system adapted to convert them into third and fourth output signals indicative of the linear drive or the rotary drive [means] displacement and direction respectively, the third and fourth output signals being compatible with the linear drive or the rotary drive [means].

27. (Twice Amended) A method of delivering a substance to a human or animal being supplied with breathable gas pressurized above atmospheric pressure, the method including [the steps of]:

continuously measuring the pressure of [the] a supplied breathable gas;

detecting inhalation by the human or animal; and

delivering [the] a substance to the human or animal during [the] an inhalation at a pressure that exceeds the pressure of [the] a supplied pressure of the breathable gas by a predetermined [amount] pressure difference.

33. (Amended) A method as claimed in claim 27, including [the steps of] measuring the volumetric flow rate of the breathable gas with an airflow sensor and generating a first input signal indicative of the breathable gas flow rate.

34. (Amended) A method as claimed in claim 33, including [the step of] amplifying the first signal into a second signal also indicative of the breathable gas flow rate.

35. (Amended) A method as claimed in claim 33, including [the step of] differentiating the first signal into a third signal indicative of breathable gas acceleration or deceleration to indicate inhalation or exhalation respectively.

36. (Amended) A method as claimed in claim 27, including [the step of] measuring the volume of the substance to be delivered to the human or animal.

38. (Amended) A method as claimed in claim 37, including [the step of] amplifying the fourth input signal into a fifth input signal also indicative of the breathable gas pressure.

40. (Amended) A method as claimed in [any one of] claim 39, wherein the positive displacement pump is a diaphragm pump.

41. (Amended) A method as claimed in [any one of] claim 40, wherein the diaphragm pump is in fluid communication with a substance reservoir via a one-way valve adapted to allow the substance to only pass from the reservoir to the diaphragm pump.

42. (Amended) A method as claimed in claim 40, wherein the diaphragm pump is [also] adapted to be in fluid communication with the gas supply conduit via a one-way valve adapted to allow the substance to only pass from the diaphragm pump to the conduit.

44. (Amended) A method as claimed in [any one of] claim 43, wherein the linear drive [means] is an electromagnet.

45. (Amended) A method as claimed in claim 40, wherein the diaphragm pump is displaced by a rotary to linear converter driven by a rotary drive [means].

46. (Amended) A method as claimed in claim 45, wherein the rotary drive means is at least one of an electric DC motor, an electric AC motor, a stepper motor [or] and a brushless motor.

47. (Amended) A method as claimed in claim 43, further including [the steps of] inputting the second, third, fourth, fifth input signals and a predetermined sixth input signal indicative of the volume of the substance to be delivered and a predetermined seventh input signal indicative of the [amount] pressure difference by which the pressure of the delivered substance should exceed the pressure of the breathable gas into a first control means and the first control system adapted to generating a first output signal indicative of the

amount of displacement of the drive means and a second output signal indicative of the direction of the displacement required to produce negative or positive pumping pressure.

49. (Amended) A method as claimed in claim 48, further including [the steps of] inputting the first and second output signals into a second control system and the second control system [adapted] converting them into third and fourth output signals indicative of drive means displacement length and direction respectively, the third and fourth output signals being compatible with the linear or rotary drive means.

New claims 50-74 have been added.

IN THE ABSTRACT OF THE DISCLOSURE:

The abstract is changed as follows:

A substance delivery apparatus [(10)] for use with a system [(12)] for supplying breathable gas to a human or animal [. The apparatus] includes [means (22)] a sensor to measure the pressure of the supplied breathable gas [means (22)] and to detect inhalation by the human or animal; and [means] a reservoir, a conduit, a pump, and a diaphragm [(54, 56, 58, 60)] to deliver the substance [(52)] to the human or animal during inhalation at a pressure higher than the supplied pressure of the breathable gas. [A method of delivering a substance (52) is also disclosed.]

End of Appendix